July 1, 2019

Asahi Intecc Co., Ltd.
% Candace Cederman
Principal Consultant
CardioMed Device Consultants, LLC
1783 Forest Drive, #254
Annapolis, Maryland 21401

Re: K183062
Trade/Device Name: ASAHI Silverway
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 31, 2019
Received: June 3, 2019

Dear Candace Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth Cavanaugh, Ph.D.
Director (Acting)
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183062

Device Name
ASAHI® Silverway®

Indications for Use *(Describe)*

This product is intended for use in the percutaneous introduction of catheters.
Not for use in the coronary arteries or intracranial vessels.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(as required by 21 CFR 807.92)

ASAHI INTECC CO.,LTD.
3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Tel. +81-561-48-5551 Fax. +81-561-48-5552
Branch office: Tokyo, Nagoya, Osaka, Hong Kong, EU, Singapore, Beijing, India, Middle Eastern
Research Facilities and Factories: Osaka, Seto, Thailand, Hanoi

ASAHI® Silverway®
510(k) K183062

Date Prepared:	28 June 2019
Applicant:	ASAHI INTECC CO., LTD. 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan
Contact:	Yoshi Terai President/CEO ASAHI INTECC USA, Inc. 3002 Dow Avenue, Suite 212 Tustin, CA 92780 Tel: (949) 756-8252, FAX: (949) 756-8165 e-mail: ASAHI.ra-fda@ASAHI-intecc.com
Trade Name:	ASAHI® Silverway®
Device Classification:	Class 2 per 21 CFR §870.1330
Classification Name:	Catheter, Guide, Wire
Product Code:	DQX – Catheter Guide Wire
Primary Predicate Device:	EMERALD Guidewire, K935170
Reference Devices:	RADIFOCUS Glidewire, K863138 ASAHI CHIKAI, K110584 ASAHI CHIKAI black, K141751 ASAHI SOFT, K022762 ASAHI Gladius Mongo, K180784 ASAHI Gladius, K150445

INTENDED USE/INDICATIONS FOR USE:

This product is intended for use in the percutaneous introduction of catheters. Not for use in the coronary arteries or intracranial vessels.

DEVICE DESCRIPTION:

The ASAHI Silverway consists of a one-piece core wire and a coil assembly that extends the entire length of the device. The coil assembly consists of an inner coil and an outer coil, soldered to the core wire. In addition, coatings are applied on the surface of the ASAHI Silverway. The distal and proximal sections are coated with silicone. The intermediate section is coated with hydrophilic coating. The ASAHI Silverway has a nominal outer diameter of

0.89mm (0.035in) and is available in various lengths from 150cm to 300cm and tip shapes.

COMPARISON WITH PREDICATE DEVICES:

Comparisons of the ASAHI® Silverway® and predicate / reference devices show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate and reference devices. The ASAHI Silverway and predicate device are constructed with a core wire covered by a coil. The available lengths and tip shapes of the ASAHI Silverway are within the ranges of the predicate and reference devices. Currently, the ASAHI Silverway is available in an 0.035" diameter which is within the range of the sizes available for the predicate and reference devices. The ASAHI Silverway has both a hydrophilic and hydrophobic (silicone) coating, whereas the predicate and reference devices have either a hydrophilic or hydrophobic coating. The intended use of the subject device and its predicates are the same.

Name of Devices	**ASAHI Silverway**	**EMERALD Guidewire**	**RADIFOCUS Glidewire**
	Subject	Predicate	Reference
510(k)	K183062	K935170	K863138
Intended Use and Indications	This product is intended for use in the percutaneous introduction of catheters. Not for use in the coronary arteries or intracranial vessels.	Cordis Guidewires are intended for use in the percutaneous introduction of catheters.	The Glidewire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.
Nominal OD	0.89mm (0.035in)	0.46~1.65mm (0.018~0.065in)	0.46~0.97mm (0.018~0.038in)
Overall Length	150~300cm	80~260cm	30~300cm
Outer Coil	Stainless Steel	Stainless Steel	NA
Tapered Core Wire	Stainless Steel	Stainless Steel	Ni-Ti
Inner Structure	Stainless Steel Coil	Stainless Steel Safety Wire	NA
Tip Shape	Angle J-tip	Straight J-tip	Straight Angle J-Tip
Coating	Silicone Hydrophilic	PTFE	Hydrophilic
Sterilization	Provided sterile via Ethylene Oxide to SAL 10^{-6}	Provided sterile via Ethylene Oxide	Provided sterile via Ethylene Oxide

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the ASAHI® Silverway® to determine substantial equivalence. The following testing/assessments were performed:

Non-clinical laboratory testing was performed on the ASAHI Silverway to determine substantial equivalence. The following testing/assessments were performed:

- Dimensional Verification
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adhesion
- Catheter Compatibility
- Radiopacity, ISO 11070
- Corrosion, ISO 11070

The *in vitro* bench tests demonstrated that the ASAHI Silverway met all acceptance criteria and performed similarly to the predicate devices. Performance data demonstrate that the device functions as intended and has a safety and effectiveness profile that is similar to the predicate devices.

BIOCOMPATIBILITY:

The ASAHI Silverway was tested in accordance with ISO 10993 and found to be biocompatible. The following tests were performed.

Cytotoxicity	ISO 10993-5: Tests for *in vitro* cytotoxicity
Intracutaneous Reactivity/Irritation	ISO 10993-10: Tests for irritation and skin sensitization
Sensitization	ISO 10993-10: Tests for irritation and skin sensitization
Acute Systemic Toxicity	ISO 10993-11: Tests for systemic toxicity
Material Mediated Pyrogenicity	USP, General Chapter <151>, ISO 10993-11: Tests for systemic toxicity
Hemolysis	ASTM F756 ISO 10993-4: tests for interactions with blood
Partial Thromboplastin Time	ASTM F2382
Thrombogenicity	ISO 10993-4: tests for interactions with blood
SC5b-9 Complement Activation	ISO 10993-4: tests for interactions with blood

CONCLUSION:

The ASAHI® Silverway® has identical intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate and reference devices.

Therefore, the ASAHI Silverway is substantially equivalent to the predicate devices.